510(k) Summary of Substantial Equivalence

Date Prepared	September 16, 2004
Submitter	CryoCor, Inc.
Address	9717 Pacific Heights Blvd. San Diego, Ca 92121
Contact	Jami Miller Regulatory Affairs Specialist
Phone	858-909-2231
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E-Mail Address	jmiller@cryocor.com
Device Trade Name/ Model Numbers	1255 Series Surgical Probe: Model 1255-15-12
Device Common Name	Cryosurgical Probe
Device Classification Name	Cryosurgical unit and accessories
Classification Regulation	Class II, C.F.R. Section 878.4350
Product Code	GEH

Device Description

The CryoCor Model 1255 Surgical Probe is a single-use, disposable device that interfaces with the Cryoablation console and delivers Cryoablation therapy to the target tissue, using N2O as a cryogen and employing the Joule-Thomson effect to cause a block of electrical conduction through tissue through cryonecrosis. Placement of the Probe tip is accomplished under direct visualization by manipulation of the Probe handle (applying torque to the shaft and/or deflecting the articulation segment). The Breva Model Series may include multiple articulation lengths and multiple tip lengths. The first model of the Breva Model Series to be commercialized will be the Breva 1255-15-12 (i.e. 5cm articulation length, 15 mm tip length, and 12cm shaft length).

Intended Use

The CryoCor Model 1255 Surgical Probe is intended to be used for the treatment of cardiac diseases, such as arrhythmia, by the application of extreme cold in order to ablate (destroy) electrically abnormal cardiac and vascular tissue. The Probe is part of a

Cryoablation System, which includes a control console and a Probe/console interface. The Probe will be used under direct visualization to perform cardiac ablation procedures in the cardiac surgical setting. The intent of the device will be to treat patients either concomitant with or using techniques widely used in cardiac surgery, including thoracotomy or minimally invasive (MICS) techniques.

Substantially Equivalent Devices

The physical characteristics, the intended use, and the mode of use of the Model 1255 Surgical Probe are similar to the predicate device.

Test Summary

Performance Testing
Bench testing confirmed that the Model 1255-15-12 Surgical Probe met its design and performance requirements.

Biocompatibility Information
Biocompatibility testing was performed on the materials which are blood contacting according to ISO 10993-1. All materials were found to be biocompatible.

Sterilization Validation
The Model 1255-15-12 Surgical Probes are sterilized using a validated E-beam radiation sterilization cycle.

Conclusion

CryoCor, Inc. considers the Model 1255-15-12 Surgical Probe to be substantially equivalent to their legally marketed predicate device based on the data and information presented within this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Cryocor, Inc.
c/o Ms. Jami Miller
Regulatory Affairs Specialist
9717 Pacific Heights Blvd.
SanDiego, CA 92121

Re: K041890
Trade Name: Cryocor Model 1250 ("Breva") Series Surgical Probes
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: II (two)
Product Code: OCL
Dated: August 05, 2004
Received: August 09, 2004

Dear Ms. Miller:

This letter corrects our substantially equivalent letter of September 22, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K041890**

Device Name: CryoCor Model 1250 ("Breva") Series Surgical Probes

Indications for Use:

The CryoCor Model 1250 ("Breva") Series Surgical Probes are intended to be used in thoracic surgery, specifically for the ablation of arrhythmic cardiac tissue.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K041890